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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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MICHAEL W. HAAS
RESPIRONICS, INC.
1010 MURRY RIDGE LANE
MURRYSVILLE, PA 15668

EXAMINER	
EREZO, DARWIN P	
ART UNIT	PAPER NUMBER
3773	

MAIL DATE	DELIVERY MODE
03/19/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/796,585	O'DEA, JOHN	
	Examiner	Art Unit	
	Darwin P. Erezo	3773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 December 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *17-30* is/are pending in the application.

4a) Of the above claim(s) *27-29* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *17-26 and 30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

1. Applicant's arguments regarding the Rajan reference failing to teach or suggest that PEEP is determined based on an average PEEP has been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of the combination of Rajan and Itoh, as provided below. Thus, this Office action is a Non-Final Office action.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. Claims 17, 18, 20-22, 24, 25 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,660,170 to Rajan et al. in view of US 4,444,201 to Itoh.

(claim 17) Rajan discloses an apparatus for providing pressure support comprising:

-a gas flow generating system **6**;

-monitoring means **8**; and

-controlling means **14**.

Rajan discloses that the apparatus delivers inspiration pulses having a starting pressure at PEEP level and an end pressure at PIP level (col. 6, ll. 27-32). The PEEP is disclosed to have any value larger than or equal to zero, but is normally lower than 20 cmH2O when determining the opening pressure (col. 6, ll. 32-34). However, the PEEP can also be above this value if it is necessary to open a collapsed lung (col. 6, ll. 37-39). Thus, PEEP is used as the “opening pressure”, which is maintained during the expiratory phase of a breathing cycle.

Rajan also discloses that several identical inspiration pulses can be provided to determine the “opening pressure”, that is, respiratory gas flow for the identical inspiration pulses is averaged to determine the "opening pressure” (col. 6, 46-52).

Therefore, Rajan discloses an apparatus having a controlling means for determining an average respiratory gas flow to determine the “opening pressure”, or PEEP, and controls the gas flow generating system such that at least a portion of the gas delivered to the portion during the expiratory phase will correspond to the average “opening pressure”. Gas is also capable of being delivered to the patient during the expiratory phase in order to maintain the PEEP level above zero to re-inflate a collapsed lung.

Rajan discloses averaging the respiratory gas flow to determine the "opening pressure" but is silent with regards to averaging the PEEP level for each inspiration

pulses. However, it is inherent that in order to determine the "opening pressure" or PEEP, it would necessary to average the actual PEEP from the respiratory gas flow of each inspiration pulses.

However, if this is not persuasive, the examiner provides the Itoh reference to disclose that it is known in the art to average previous PEEP levels as a reference pressure for detection (col. 4, ll. 9-12), which is similar to an "opening pressure".

Thus, one of ordinary skill in the art would have found it obvious to modify the controlling means of Rajan to specifically average the PEEP levels to determine the “opening pressure” because such technique is known in the art, as taught by Itoh, and that averaging the actual PEEP levels will provide the best value for the "opening pressure".

Furthermore, even without the Itoh reference, one of ordinary skill in the art would have found it obvious to average PEEP levels to determine the “opening pressure” since the opening pressure is taught to be based on the PEEP level.

(claim 18) As seen in Fig. 2, a portion of the pressure level during the inspiratory phase is higher than the baseline PEEP.

(claims 20 and 22) The monitoring means **8** is proximate the airway of the subject, wherein the monitoring means is connected to the controlling means via a wire (shown in the circuit diagram of Fig. 2). It is also noted that the term “proximate” is a relative term.

(claim 21) Fig. 2 shows a circuit diagram of the device being connected to the patient. Therefore, it would be inherent for the system to have a patient circuit interface for the device to deliver the oxygen to the patient.

(claim 24) Rajan discloses a pressure gauge/transducer **10**.

(claim 25) The device of Rajan is fully capable of being portable.

(claim 30) Rajan also discloses the method of providing the device about to deliver a flow of gas to a patient, wherein the PEEP and other respiratory parameters are determined; and wherein the pressure of gas delivered to the patient is controlled based on the average of these parameters.

5. Claims 19 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rajan et al. in view of Itoh, as applied in the rejections to claim 17 above, and in further view of US 5,551,419 to Froechlich et al.

Rajan discloses a device gas flow generating system having a regulating unit **2**, which is Servo Ventilator 300, and the controlling means **14** controlling the pressure supplied by the gas flow generating system **6**. Rajan is silent with regards to how the gas flow generating system is controlled by the controlling unit (e.g., by controlling the speed of the blower). However, Froechlich discloses a similar device having a gas flow generating system **12** and a controlling means **17**, wherein gas flow generating system is a blower. Therefore, since both gas flow generating system are well known in the prior art and both perform the function of regulating the amount of gas pressure delivered to a patient, one of ordinary skill in the art would have found it obvious to replace the gas flow generating system of Rajan with the system taught by Froechlich.

6. Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over Rajan et al. in view of Itoh, as applied to the rejections to claim 17 above, and in further view of US 5,868,133 to DeVries et al.

Rajan is silent with regards to the monitoring means being connected to the controlling means via a wireless signal. However, DeVries teaches a medical device in which components are connected via hard wire or wireless (col. 12, lines 41-43). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to replace the hard wire connection of Rajan with a wireless connection because using a wireless connection or hard wire connection is a mere design choice that would be available to one of ordinary skill in the art.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Darwin P. Erezo whose telephone number is (571)272-4695. The examiner can normally be reached on M-F (8:00-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Darwin P. Erezo/
Primary Examiner, Art Unit 3773